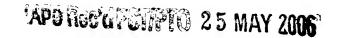
PTO-1390 (Rev. 07-2005) Approved for use through 03/31/2007. OMB 0651-0021

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## TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER 4705-0120PUS1

PRIORITY DATE CLAIMED **CONCERNING A SUBMISSION UNDER 35 U.S.C. 371** INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PCT/BR2004/000235 25 November 2004 28 November 2003 TITLE OF INVENTION READY-FOR-USE INJECTABLE SOLUTION OF 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6(9H)-ONE, STERILE, STABLE; CLOSED SYSTEM FOR PACKING THE SOLUTION, PROCESS FOR ELIMINATING ALKALINE 🔒 🕠 RESIDUALS OF 9-((1,3-DIHYDROXYPROPAN-2-ILOXY)METHYL)-2-AMINE-1H-PURIN-6 (9H)-ONE CRYSTALS; PHARMACEUTICAL PRESENTATION AS A CLOSED SYSTEM READY-FOR-USE; USES AND METHODS APPLICANT(S) FOR DO/EO/US Heno PERILLO; Jose CAMPOS NETO; and Marcio CRUCELLI Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: 1. x This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. X The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). C. An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7. x Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. A preliminary amendment. 14. x An Application Data Sheet under 37 CFR 1.76. 15. A substitute specification. 16. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18 A second copy of the published International Application under 35 U.S.C. 154(d)(4). 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).



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U.S. APPLI 10/580651 INTERNATIONAL APPLICATION NO. PCT/BR2004/000235				ATTORNEY'S DOCKET NUMBER 4705-0120PUS1			
	items or informa	ation: Return	Receipt Postcard	24 Amondo			
		PUI/IS	SA/210; Letter Submit	tting Article 34 Amendr	ments		
_	-	e been submitte			CALCULAT		PTO USEONLY
21. x Basic	; national fee (3	37 CFR 1.492(a	))	\$300	\$ 30	00.00	
22. x Examination fee (37 CFR 1.492(c))  If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)(4)\$0  All other situations \$200						00.00	
23. X Search fee (37 CFR 1.492(b))  If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0  Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100  International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB. \$400						\$ 400.00	
All other situations					\$ 90	\$ 900.00	
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof.						0.00	
Total Sheets	Extra Sheets Number of each additional 50 or fraction thereof (round up to a whole number)			RATE			
37 -100=	/50 =			x \$250.00	\$		
after the date of co	commencement of	the national stage	, examination fee, or the (37 CFR 1.492(h)).		\$ 13	0.00	
CLAIMS		MBER FILED	NUMBER EXTRA	RATE			
Total claim	·- ,	9-20 =		x		0.00	
Independent claims 2 - 3 =  MULTIPLE DEPENDENT CLAIM(S) (if applicable)				<b>X</b>		0.00	
TOTAL OF ABOVE CALCULATIONS =						\$ 1,030.00	
Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					Ψ 1,00	0.00	
SUBTOTAL =					\$ 1,03	\$ 1,030.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).					\$		
TOTAL NATIONAL FEE =					\$ 1,030.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property					\$		
					\$		
TOTAL FEES ENCLOSED =					\$ 1,030.00		
					Amount to be refunded:		
					Amount to be charged	s be \$	

## 10/580651 APPROCUPETATED 25 MAY 2006

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U. S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. a. X A check in the amount of \$ 1,030.00 to cover the above fees is enclosed. Please charge my Deposit Account No. 02-2448 in the amount of \$ \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed. c. x The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448 . A duplicate copy of this sheet is enclosed. Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038 NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed an granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: Maan (Ronard, Obe) May 25, 2006 Mark J. Nuell, Ph.D. CUSTOMER NUMBER: 02292 36,623 REGISTRATION NUMBER /clb

## LAPS ROL'S PETITION 25 MAY 2005

Docket No.: 4705-0120PUS1

(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Heno PERILLO et al.

Application No.: NEW

Filed: May 25, 2006

Art Unit: N/A

For: READY-FOR-USE INJECTABLE SOLUTION
OF 9-((1,3-DIHYDROXYPROPAN-2ILOXY)METHYL)-2-AMINE-1H-PURIN6(9H)-ONE, STERILE, STABLE; CLOSED
SYSTEM FOR PACKING THE SOLUTION,
PROCESS FOR ELIMINATING ALKALINE
RESIDUALS OF 9-((1,3DIHYDROXYPROPAN-2-ILOXY)METHYL)2-AMINE-1H-PURIN-6 (9H)-ONE CRYSTALS;
PHARMACEUTICAL PRESENTATION AS A

Examiner: Not Yet Assigned

Confirmation No.: N/A

**CLOSED SYSTEM READY-FOR-USE; USES** 

**LETTER** 

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

AND METHODS

Sir:

The PTO is requested to use the amended sheets/claims attached hereto (which correspond to Article 19 amendments or to claims attached to the International Preliminary Examination Report (Article 34)) during prosecution of the above-identified national phase PCT application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

Application No.: NEW Docket No.: 4705-0120PUS1

Dated: May 25, 2006

Respectfully submitted,

Mark N Nuell, Ph.D.

Registration No.: 36,623

BIRCH, STEWART, KOLASCH & BIRCH, LLP

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Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant

Attachment(s)

2 DRN/clb